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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,010	03/06/2006	Elizabeth Ann Webb	2349.0010000/JUK/MEK	2794

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005

EXAMINER
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BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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03/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,010	<b>Applicant(s)</b> WEBB ET AL.	
	<b>Examiner</b> Michael Borin	<b>Art Unit</b> 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5-9 and 12-30 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,5-9, 12-30 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

Claims 1,5-9, 12-30 are pending.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1,5,6, drawn to method for designing a candidate polypeptide.

Group II, claim(s) 7, 12(in part), drawn to method for designing a candidate polypeptide by arranging epitopes from two groups.

Group III, claim(s) 8, 12(in part), drawn to method for designing a candidate polypeptide by arranging epitopes from three groups.

Group IV claim(s) 9, 12(in part), drawn to method for designing a candidate polypeptide by arranging epitopes from four groups.

Group V, claim(s) 13, drawn to method of expressing polypeptide.

Group VI, claim(s) 14,15, 17(in-part),drawn to polypeptides.

Group VII, claim(s) 16, 17(in-part), drawn to polypeptides.

Group VIII, claim(s) 18, drawn to first vaccine.

Group IX, claim(s) 19(in-part), 20, drawn to polypeptide SEQ ID No. 1.

Group X, claim(s) 19(in-part), 21, drawn to polypeptide SEQ ID No. 2.

Group XI, claim(s) 19(in-part), 22, drawn to polypeptide SEQ ID No. 3.

Group XII, claim(s) 19(in-part), 23, drawn to polypeptide SEQ ID No. 4.

Group XIII, claim(s) 19(in-part), 24, drawn to polypeptide SEQ ID No. 5.

Group XIV, claim(s) 25(in-part), drawn to vaccine comprising polypeptide SEQ ID No. 1.

Group XV, claim(s) 25(in-part), , drawn to vaccine comprising polypeptide SEQ ID No. 2.

Group XVI, claim(s) 25 (in-part), drawn to vaccine comprising polypeptide SEQ ID No. 3.

Group XVII, claim(s) 25(in-part), drawn to vaccine comprising polypeptide SEQ ID No. 4.

Group XVIII, claim(s) 25(in-part), drawn to vaccine comprising polypeptide SEQ ID No. 5.

Group XIX, claim(s) 26, drawn to first vaccine comprising polynucleotide.

Group XX, claim(s) 27, drawn to second vaccine comprising polynucleotide.

Group XXI, claim(s) 28, 17(in-part), drawn to polypeptide designed by method of claim 7.

Group XXII, claim(s) 29, 17(in-part), drawn to polypeptide designed by method of claim 7.

Group XXIII, claim(s) 30, 17(in-part), drawn to polypeptide designed by method of claim 7.

The inventions listed as Groups I-XXIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I is the technical feature that links Groups I-XXIII. Group I is not the contribution over the prior art because it is suggested by references teaching methods of modifying polypeptide structure to generate candidate polypeptide with reduced amplitude in hydrophobicity or length of a hydrophobic region. See, for example, Tsitrin et al. (Nature. Structural Biology, 2002, vol. 9(10), 729-733) or Bentzien et al (US 2003/0130827). Therefore, the lack of unity is present because the linking technical feature is not a "special technical feature" as defined by PCT Rule 13.2.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

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are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin, Ph.D./  
Primary Examiner, Art Unit 1631

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